

Congressionally Directed Research Will Improve Outcomes Through Funding Opportunities for Orthopaedics

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Abstract

The large funding opportunities created by the US Congress have allowed the military and civilian orthopaedic communities to collaborate to define clinical problems and develop solutions. It is believed that this research effort will be constructive in the short term because of emphasis placed on funding projects that used relevant populations and approaches that will benefit patients soon. The immediate results will define best practice guidelines. Additionally, new therapies will be fielded that will reduce complications and improve the outcomes of both injured service personnel and civilians.

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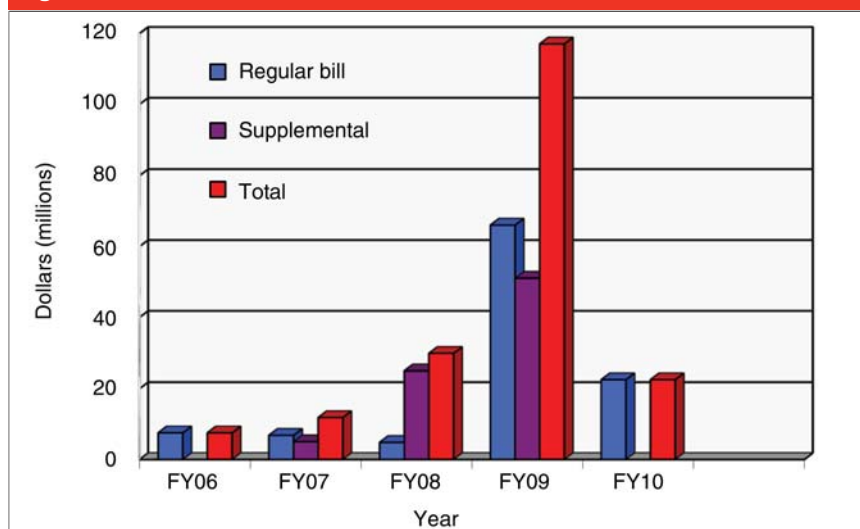
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The United States has been at war for almost a decade, and tens of thousands of service personnel have been killed in action, died of wounds, or been wounded in action during this period. It has long been suggested that the only real winner in war is medicine, and this notion is supported by the countless medical advances made during wartime throughout history. Much of the medical and research efforts in previous wars focused on reducing mortality, and the initial efforts in the recent conflicts indicated that this trend would continue. Development and early deployment of improved hemostatic bandages and tourniquets, along with other advances, saved lives and decreased mortality rates. Although costly on the service personnel, the long duration of the military operations did serve a purpose: it allowed sufficient time for a better and more comprehensive understanding of the wound patterns, surgical procedures, complications,

medical expense, and outcomes of the casualties while the fighting continued.

Fortunately, an acute awareness that the vast majority of casualties live, and that the survivors often have poor outcomes, arose fairly early in the present conflicts; moreover, it became evident that most of the morbidity is caused by orthopaedic conditions. This can be attributed to the fact that the extremities are the most commonly wounded body regions and that most extremity injuries are survivable. In fact, 82% of battlefield-injured combat personnel have had at least one extremity injury.¹ Penetrating soft-tissue injury and open fractures account for most of these wounds and are the source of the most common complications—infection, nonunion, and heterotopic ossification. Degenerative arthritis, impairment and/or loss of muscle and nerve function, pain, and spine conditions are some of the most common outcomes for

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Figure 1

Congressionally directed orthopaedic research funding from fiscal year (FY) 2006 through 2010 in millions of dollars. Regular and supplemental bills, along with the total funding, are shown. Funding in 2006, 2007, and 2008 was assigned to the Orthopaedic Extremity Trauma Research Program, along with \$5 million from the 2009 regular bill. The Peer Reviewed Orthopaedic Research Program manages the remaining \$112 million from the 2009 regular bill and all of the 2010 funding.

battlefield-injured personnel, superseding the highly visible major limb amputation as the most common reasons for medical separation from service.² These extremity injuries account for approximately two-thirds of inpatient hospital costs and resulting disability payments.³ Orthopaedic injuries are the primary burden of disease and the largest source of morbidity from war.

Orthopaedic Extremity Trauma Research Program

For decades, the US Congress has appropriated funds for extramural medical research programs con-

ducted through the Department of Defense (DoD) to address the specific medical research needs of the DoD, as well as other topics of defined importance to Congress. In the 2005 Department of Defense Appropriations Act, for the first time, in response to information presented by the American Academy of Orthopaedic Surgeons (AAOS) implicating extremity injury as a source of substantial morbidity among wounded service personnel, Congress listed extremity trauma as a funding priority for the DoD. No specific funds were provided at that time.

The Orthopaedic Extremity Trauma Research Program (OETRP)

was first funded by Congress in fiscal year 2006 (FY 06) and received funding through FY 09. The initial appropriation of \$7.5 million in 2006 (Figure 1) led to an important coordinated effort between military and civilian surgeons to define problems, evaluate practice, and identify research priorities.⁴ The OETRP was initially created within Title IV of the 2006 Department of Defense Appropriations Act as part of the congressional allocation to the army for research, development, test, and evaluation (RDT&E). It was therefore established and managed by the US Army Institute of Surgical Research in partnership with the orthopaedic community of the three military services and in close consultation with civilian orthopaedic trauma specialists.

An initial program announcement was created using the Prioritized Research Objectives established at the first AAOS Extremity War Injuries Symposium as a template.⁴ Initial research topics focused on the acute management of wounds and on reducing complications.⁵ Based on the overall amount of funding available in the context of a desire to promote investigation in several areas, initial grants were limited to a maximum of \$500,000 per year. This amount necessarily limited the ability to fund clinical trials, particularly large prospective randomized studies, which are typically orders of magnitude more expensive than preclinical studies. Thus, most submissions represented basic science or translational proposals. Proposals were peer reviewed, and a competitive two-tiered

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review process was developed to rank the proposals on the basis of (1) military impact, (2) military relevance, and (3) scientific merit. Studies with the possibility of delivering meaningful clinical information to military orthopaedic surgeons within 5 years received funding priority.

This process was used for both the FY 06 and FY 07 appropriations to fund 26 of 244 proposals. Most proposals that received funding were translational or small clinical studies. Because available funding was extremely limited, only the first year of support was guaranteed for any multiyear proposal. Subsequent years were to be funded with future years' appropriations based on successful achievement of defined milestones by the investigators, assuming sufficient funds were provided by Congress to allow continuation. A complete list of funded proposals can be found on the OETRP Web site.⁵

This funding limitation led to several problems. Researchers who accepted these restrictions needed to be able to put projects on hold or to abort them if Congressional funding for OETRP did not continue in subsequent years. This meant that many high-quality research laboratories sought other avenues, and often other topics, for focus to have a better chance of achieving longer-term support. The restriction also limited the ability to conduct large prospective clinical studies because there were considerable ethical challenges associated with enrolling patients in trials that had a substantial chance of being cancelled before completion because of discontinued funding.

In 2008, based on demonstrated success in developing an effective peer-review process and on demonstrated need for further knowledge to advance care of wounded service personnel, Congress appropriated a total of \$29.8 million in US Army RDT&E funds for orthopaedic

trauma research (Figure 1). This major increase in funding was used to accomplish two things. First, funds were allocated to support the entire period of the initial grant award for many of the projects funded in 2006 and 2007. Second, this funding allowed for the development of a meaningful clinical research program.

Prospective randomized clinical trials (RCTs) offer the highest level of evidence and have the greatest likelihood of improving the quality of care military orthopaedic surgeons are able to provide to wounded personnel. A multicenter, clinical trials consortium offers the opportunity to enroll study participants at a faster rate and to achieve economies of scale by using a single coordinating center to provide oversight, data management, and protocol development functions. The substantial increase in funding in 2008 allowed the OETRP to develop a consortium. After an open, competitive, peer-reviewed process, the OETRP provided \$21.5 million to establish the Major Extremity Trauma Research Consortium (METRC). This represented the largest single federal grant award in the history of orthopaedic trauma research and offered the first real hope of effectively performing RCTs to effectively address the high-energy extremity injuries currently plaguing the military. METRC is based at the Johns Hopkins University Bloomberg School of Public Health in Baltimore, Maryland. Twelve civilian centers and the four largest DoD medical treatment facilities served as the initial clinical operational bases for the consortium.⁶ Thirty other clinical centers were designated as satellite centers for patient enrollment with the potential opportunity to serve as core centers if they demonstrate effectiveness in enrolling patients or if additional funding becomes available to the

consortium to support expansion. The OETRP award funded three prospective RCTs related to challenges in high-energy extremity trauma (fracture fixation, treatment of infection, and reconstruction of bone defects). The consortium is also maintaining a detailed registry of high-energy orthopaedic injuries among patients admitted to participating centers.

Peer Reviewed Orthopaedic Research Program

In FY 09, Congress directed a shift in funding for orthopaedic research. The focus was expanded beyond acute care to include definitive care and rehabilitation, and the level of funding was substantially increased. The Congressionally Directed Medical Research Programs, a subordinate office of the US Army Medical Research and Materiel Command, was assigned responsibility for managing the \$112 million in appropriations (Figure 1), and the Peer Reviewed Orthopaedic Research Program (PRORP) was created. The program set a vision of providing all service personnel with orthopaedic injuries sustained in the defense of the Constitution the opportunity for optimal recovery and restoration of function. The PRORP released seven program announcements, challenging the scientific community to design innovative research to foster new directions for, and address neglected issues in, combat-relevant orthopaedic problems.⁷ The funding mechanisms ranged from small, hypothesis-driven awards with a \$100,000 budget limit to a \$40 million Clinical Consortium Award to create a broad research portfolio of basic, translational, and clinical studies. The PRORP used a two-tier review process to first evaluate the

scientific merit of each proposal and then make funding recommendations based on the relative scientific merit, portfolio balance, and programmatic relevance of the submissions. Eighty-three research projects representing more than \$100 million for research were funded during the initial year of PRORP, including six clinical trials and a clinical consortium. This is an enormous effort to improve the outcomes of injured service personnel.

The previously OETRP-funded consortium, METRC, received the FY 09 PRORP Clinical Consortium Award. The award allows METRC to expand the number of enrolling civilian centers to 24, conduct 4 additional clinical studies, and provide research support to the 4 partnering DoD medical treatment facilities. The new studies will expand the research areas to include defining the best definitive care procedures, identifying alternatives to addictive narcotics for pain management, and re-integrating the injured into society.

The PRORP was continued by Congress with \$22.5 million in FY10 and will use the funding to create an Orthopaedic Rehabilitation Clinical Consortium. This consortium will conduct clinical studies to improve the rehabilitation of combat and combat-related neuromusculoskeletal injuries.⁸ A Career Development

Award is also being offered. This will support a mentored research experience to prepare military investigators for independent careers in orthopaedic research. The PRORP Web site has more information about its previous research awards and funding opportunities.⁷

Summary

The large funding opportunities created by Congress have allowed both the military and civilian orthopaedic communities to work together to define clinical problems and develop solutions. Although research results often take decades to mature, this effort is different. It is believed that this research effort will be constructive in the short term because emphasis was placed on funding projects that used relevant populations and approaches that will benefit patients soon. The immediate results will define best practice guidelines along with fielding new therapies that reduce complications and improve the outcomes of both injured service personnel and civilians. The OETRP and the PRORP demonstrate the value and potential of a concerted research effort toward one goal—healing the individual men and women who risk their lives to fight for our country.

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